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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,118	07/31/2001	Rolf Menzel	10424-003	5780

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EXAMINER

RIGGINS, PATRICK S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/920,118		MENZEL, ROLF	
	Examiner		Art Unit	
	Patrick S. Riggins		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 45-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,8-10,12,13,15,19-21,35,36,45,58 and 59 is/are rejected.
- 7) ☒ Claim(s) 2,3,5-7,11,14,16-18,22-34 and 46-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10-28-04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Receipt is acknowledged of the substitute amendment filed 3/8/05 in which claims 1, 11, and 13 were amended and claim 43 was cancelled. Claims 1-36 and 45-59 are currently pending and under consideration.
2. Any rejection or objection not addressed herein is withdrawn. This action is not final as there are new grounds of rejection presented herein that were not necessitated by applicant's amendment of the claims in the response filed 3/8/05.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 16 recites, "wherein the donor vector is a non-replicating plasmid." There is no specific mention of a non-replicating plasmid in the specification. It would be remedial to amend claim 16 to the language used in the specification and in claims 5, 33, 34, 55, and 56, i.e. to amend claim 16 to recite --wherein the donor vector is a suicide vector.--
4. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Attention is specifically drawn to page 31, line 6 and page 47, line 15. If the web pages listed are necessary for full support, it would be remedial to simply remove the browser executable portion of the web addresses, i.e. to remove http:// from the addresses.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, 8-10, 12-13, 15, 19-21, 35-36, 45, and 58-59 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,888,732 (hereinafter Hartley). The claims are drawn to a method for recombining vectors *in vivo* where a donor vector comprises from 5' to 3' a first donor sequence and a second donor sequence, while the target vector comprises from 5' to 3' a first target sequence, a negatively selectable marker, and a second target sequence. The negatively selectable marker can comprise a conditionally lethal sequence. The target vector can additionally comprise a gene sequence downstream of the second target sequence, such that the negatively selectable marker is a polar insert and that upon removal of the negatively selectable marker, the downstream gene can be expressed. The donor vector can further comprise a positively selectable marker. The donor and target sequences can comprises non-functional fragments of a selectable marker, which when recombined lead to the formation of a functional selectable marker. The optional positively selectable marker can be selected for prior to recombination.

7. Hartley discloses a method for recombinational cloning whereby a donor vector comprises two a gene flanked by two recombination sites and a target vector comprises a gene, which can be a selectable marker, flanked by two recombination sites (see Figures 1, 2A, 3A, and 4A, columns 1, 2, 45, 8-14, 16, and 17, and Examples 3 and 6). The clearest example of how

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this patent anticipates these claims can be found in columns 9 and 10. Here the system is fully described. The selectable markers can be positive or negative depending upon the needs of the assay. Referring to Figure 1 of Hartley, (A) can be a positively selectable marker or (C) can be a negatively selectable marker. In either instance the artisan could select for the desired product (A/D) at the expense of the undesirable product (C/B). Additionally, Hartley discloses a method whereby a selectable marker is reconstituted due to recombination: "A third Vector Donor embodiment comprises a first DNA segment and a second DNA segment, the first or second DNA segment comprising an inactive fragment of at least one Selectable marker, wherein the inactive fragment of the Selectable marker is capable of reconstituting a functional Selectable marker when recombined across the first or second recombination site with another inactive fragment of at least one Selectable marker" (column 5, lines 30-37). The recombination methods can be performed *in vitro* or *in vivo*, which would require transformation steps. Figure 4A depicts a method whereby a gene of interest, namely *cam* is in a state where it cannot be expressed until after integration where it is then placed downstream of the CMV promoter, thus the recombination has removed the sequences in CMVcoint that prevent the expression of *cam* from the CMV promoter.

Conclusion

8. Claims 2, 3, 5-7, 11, 14, 16-16, 22-34, and 46-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102.

The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.
Examiner
Art Unit 1636



JAMES KETTER
PRIMARY EXAMINER